

NOTICE OF FINAL RULEMAKING
TITLE 4. PROFESSIONS AND OCCUPATIONS
CHAPTER 16. ARIZONA MEDICAL BOARD

ARTICLE 1. GENERAL PROVISIONS

R4-16-101. Definitions

ARTICLE 6. DISCIPLINARY ACTIONS

R4-16-603. Acts of Unprofessional Conduct

ARTICLE 7. OFFICE-BASED SURGERY USING SEDATION

R4-16-701. Health Care Institution License

R4-16-702. Administrative Provisions

R4-16-703. Procedure and Patient Selection

R4-16-704. Sedation Monitoring Standards

R4-16-705. Perioperative Period; Patient Discharge

R4-16-706. Emergency Drugs; Equipment and Space Used for Office-Based Surgery Using Sedation

R4-16-707. Emergency and Transfer Provisions

TITLE 4. PROFESSIONS AND OCCUPATIONS
CHAPTER 16. ARIZONA MEDICAL BOARD
ARTICLE 1. GENERAL PROVISIONS

R4-16-101. Definitions

Unless the context otherwise requires, definitions prescribed under A.R.S. § 32-1401 and the following apply to this Chapter:

1. "ACLS" means advanced cardiac life support performed according to certification standards of the American Heart Association.
2. "Agent" means an item or element that causes an effect.
3. "Approved medical assistant training program" means a program accredited by any of the following:
 - a. The Commission on Accreditation of Allied Health Education Programs;
 - b. The Accrediting Bureau of Health Education Schools;
 - c. A medical assisting program accredited by any accrediting agency recognized by the United States Department of Education; or
 - d. A training program:
 - i. Designed and offered by a licensed allopathic physician;
 - ii. That meets or exceeds any of the prescribed programs in subsection (a), (b), or (c); and
 - iii. That verifies the entry-level competencies of a medical assistant prescribed under R4-16-402(A).
4. "Auscultation" means the act of listening to sounds within the human body either directly or through use of a stethoscope or other means.
5. "BLS" means basic life support performed according to certification standards of the American Heart Association.
6. "Capnography" means monitoring the concentration of exhaled carbon dioxide of a sedated patient to determine the adequacy of the patient's ventilatory function.
7. "Deep sedation" means a drug-induced depression of consciousness during which a patient:
 - a. Cannot be easily aroused, but
 - b. Responds purposefully following repeated or painful stimulation, and
 - c. May partially lose the ability to maintain ventilatory function.

8. "Discharge" means a written or electronic documented termination of office-based surgery to a patient.
9. "Drug" means the same as in A.R.S. § 32-1901.
10. "Emergency" means an immediate threat to the life or health of a patient.
11. "Emergency drug" means a drug that is administered to a patient in an emergency.
12. "General Anesthesia" means a drug-induced loss of consciousness during which a patient:
 - a. Is unarousable even with painful stimulus; and
 - b. May partially or completely lose the ability to maintain ventilatory, neuromuscular, or cardiovascular function or airway.
13. "Health care professional" means a registered nurse defined in A.R.S. § 32-1601, registered nurse practitioner defined in A.R.S. § 32-1601, physician assistant defined in A.R.S. § 32-2501, and any individual authorized to perform surgery according to A.R.S. Title 32 who participates in office-based surgery using sedation at a physician's office.
14. "Informed consent" means advising a patient of the:
 - a. Purpose for and alternatives to the office-based surgery using sedation,
 - b. Associated risks of office-based surgery using sedation, and
 - c. Possible benefits and complications from the office-based surgery using sedation.
15. "Inpatient" has the same meaning as in A.A.C. R9-10-201.
16. "Malignant hyperthermia" means a life-threatening condition in an individual who has a genetic sensitivity to inhalant anesthetics and depolarizing neuromuscular blocking drugs that occurs during or after the administration of an inhalant anesthetic or depolarizing neuromuscular blocking drug.
17. "Minimal Sedation" means a drug-induced state during which:
 - a. A patient responds to verbal commands,
 - b. Cognitive function and coordination may be impaired, and
 - c. A patient's ventilatory and cardiovascular functions are unaffected.
18. "Moderate Sedation" means a drug-induced depression of consciousness during which:
 - a. A patient responds to verbal commands or light tactile stimulation, and
 - b. No interventions are required to maintain ventilatory or cardiovascular function.
19. "Monitor" means to assess the condition of a patient.
20. "Office-based surgery" means a medical procedure conducted in a physician's office or other outpatient setting that is not part of a licensed hospital or licensed ambulatory surgical center. (A.R.S. § 32-1401(20)).

21. "PALS" means pediatric life support performed according to certification standards of the American Academy of Pediatrics or the American Heart Association.
22. "Patient" means an individual receiving office-based surgery using sedation.
23. "Physician" has the same meaning as doctor of medicine as defined in A.R.S. § 32-1401.
24. "Rescue" means to correct adverse physiologic consequences of deeper than intended level of sedation and return the patient to the intended level of sedation.
25. "Sedation" means minimum sedation, moderate sedation, or deep sedation.
26. "Staff member" means an individual who:
 - a. Is not a health care professional, and
 - b. Assists with office-based surgery using sedation under the supervision of the physician performing the office-based surgery using sedation.
27. "Transfer" means a physical relocation of a patient from a physician's office to a licensed health care institution.

ARTICLE 6. DISCIPLINARY ACTIONS

R4-16-603. Acts of Unprofessional Conduct

A physician commits an act of unprofessional conduct when the physician violates one or more subparagraphs of A.R.S. § 32-1401(27). These statutory violations are referenced under the categories that follow.

Items 1. – 19. No change from previous rule

20. "Performing office-based surgery using sedation in violation of Board rules" includes those actions or omissions that violate A.R.S. § 32-1401(27)(tt) and Article 7 of this Chapter.
 - a. The Board may resolve a one-time violation with probation, but may issue a letter of reprimand and probation for a departure from the standard of care; and
 - b. The Board may resolve repeated or egregious violations by issuing a decree of censure and probation, suspension, or revocation.

ARTICLE 7. OFFICE-BASED SURGERY USING SEDATION

R4-16-701. Health Care Institution License

A physician who uses general anesthesia in the physician's office or other outpatient setting that is not part of a licensed hospital or licensed ambulatory surgical center when performing office-based surgery using sedation shall obtain a health care institution license as required by the Arizona Department of Health Services under A.R.S. Title 36, Chapter 4 and 9 A.A.C. 10.

R4-16-702. Administrative Provisions

- A.** A physician who performs office-based surgery using sedation in the physician's office or other outpatient setting that is not part of a licensed hospital or licensed ambulatory surgical center shall:
1. Establish, document, and implement written policies and procedures that cover:
 - a. Patient's rights,
 - b. Informed consent,
 - c. Care of patients in an emergency, and
 - d. The transfer of patients;
 2. Ensure that a staff member who assists with or a healthcare professional who participates in office-based surgery using sedation:
 - a. Has sufficient education, training, and experience to perform duties assigned;
 - b. If applicable, has a current license or certification to perform duties assigned; and
 - c. Performs only those acts that are within the scope of practice established in the staff member's or health care professional's governing statutes;
 3. Ensure that the office where the office-based surgery using sedation is performed has all equipment necessary:
 - a. For the physician to safely perform the office-based surgery using sedation,
 - b. For the physician or health care professional to safely administer the sedation,
 - c. For the physician or health care professional to monitor the use of sedation, and
 - d. For the physician and health care professional administering the sedation to rescue a patient after the sedation is administered to the patient and the patient enters into a deeper state of sedation than what was intended by the physician.
 4. Ensure that a copy of the patient's rights policy is provided to each patient before performing office-based surgery using sedation;
 5. Obtain informed consent from the patient before performing an office-based surgery using sedation that:
 - a. Authorizes the office-based surgery, and

- b. Authorizes the office-based surgery to be performed in the physician's office; and
- 6. Review all policies and procedures every 12 months and update as needed.
- B.** A physician who performs office-based surgery using sedation shall comply with:
 - 1. The local jurisdiction's fire code;
 - 2. The local jurisdiction's building codes for construction and occupancy;
 - 3. The biohazardous waste and hazardous waste standards in A.A.C. Title 18, Chapter 13, Article 14; and
 - 4. The controlled drug administration, supply, and storage standards in A.A.C. Title 4, Chapter 23.

R4-16-703. Procedure and Patient Selection

- A.** A physician shall ensure that each office-based surgery using sedation performed:
 - 1. Can be safely performed with the equipment, staff members, and health care professionals at the physician's office;
 - 2. Is of duration and degree of complexity that allows a patient to be discharged from the physician's office within 24 hours;
 - 3. Is within the education, training, experience skills, and licensure of the physician; and
 - 4. Is within the education, training, experience, skills, and licensure of the staff members and health care professionals at the physician's office.
- B.** A physician shall not perform office-based surgery using sedation if the patient:
 - 1. Has a medical condition or other condition that indicates the procedure should not be performed in the physician's office, or
 - 2. Will require inpatient services at a hospital.

R4-16-704. Sedation Monitoring Standards

A physician who performs office-based surgery using sedation shall ensure from the time sedation is administered until post-sedation monitoring begins:

- 1. A quantitative method of assessing a patient's oxygenation, such as pulse oximetry, is used when minimal sedation is administered to the patient, and
- 2. When moderate or deep sedation is administered to a patient:
 - a. A quantitative method of assessing the patient's oxygenation, such as pulse oximetry, is used;
 - b. The patient's ventilatory function is monitored by any of the following:
 - i. Direct observation,
 - ii. Auscultation, or
 - iii. Capnography;

- c. The patient's circulatory function is monitored during the surgery by:
 - i. Having a continuously displayed electrocardiogram,
 - ii. Documenting arterial blood pressure and heart rate at least every five minutes, and
 - iii. Evaluating the patient's cardiovascular function by pulse plethysmography,
- d. The patient's temperature is monitored if the physician expects the patient's temperature to fluctuate; and
- e. That a licensed and qualified healthcare professional, other than the physician performing the office-based surgery, whose sole responsibility is attending to the patient, is present throughout the office-based surgery.

R4-16-705. Perioperative Period; Patient Discharge

A physician performing office-based surgery using sedation shall ensure all of the following:

- 1. During office-based surgery using sedation, the physician is physically present in the room where office-based surgery is performed;
- 2. After the office-based surgery using sedation is performed, a physician is at the physician's office and sufficiently free of other duties to respond to an emergency until the patient's post-sedation monitoring is discontinued;
- 3. If using minimal sedation, the physician or a health care professional certified in ACLS, PALS, or BLS is at the physician's office and sufficiently free of other duties to respond to an emergency until the patient is discharged;
- 4. If using deep or moderate sedation, the physician or a health care professional certified in ACLS or PALS is at the physician's office and sufficiently free of other duties to respond to an emergency until the patient is discharged;
- 5. A discharge is documented in the patient's medical record including:
 - a. The time and date of the patient's discharge, and
 - b. A description of the patient's medical condition at the time of discharge; and
- 6. A patient receives discharge instructions and documents in the patient's medical record that the patient received the discharge instructions.

R4-16-706. Emergency Drugs; Equipment and Space Used for Office-Based Surgery Using Sedation

- A. In addition to the requirements in R4-16-702(A)(3) and R4-16-703(A)(1), a physician who performs office-based surgery using sedation shall ensure that the physician's office has at a minimum:

1. The following:
 - a. A reliable oxygen source with a SaO₂ monitor;
 - b. Suction;
 - c. Resuscitation equipment, including a defibrillator;
 - d. Emergency drugs; and
 - e. A cardiac monitor;
 2. The equipment for patient monitoring according to the standards in R4-16-704;
 3. Space large enough to:
 - a. Allow for access to the patient during office-based surgery using sedation, recovery, and any emergency;
 - b. Accommodate all equipment necessary to perform the office-based surgery using sedation; and
 - c. Accommodate all equipment necessary for sedation monitoring;
 4. A source of auxiliary electrical power available in the event of a power failure; and
 5. Equipment, emergency drugs, and resuscitative capabilities required under this section for patients less than 18 years of age, if office-based surgery using sedation is performed on these patients; and
 6. Procedures to minimize the spread of infection.
- B.** A physician who performs office-based surgery using sedation shall:
1. Ensure that all equipment used for office-based surgery using sedation is maintained, tested, and inspected according to manufacturer specifications, and
 2. Maintain documentation of manufacturer-recommended maintenance of all equipment used in office-based surgery using sedation.

R4-16-707. Emergency and Transfer Provisions

- A.** A physician who performs office-based surgery using sedation shall ensure that before a health care professional participates in or staff member assists with office-based surgery using sedation, the health care professional and staff member receive instruction in the following:
1. Policy and procedure in cases of emergency,
 2. Policy and procedure for office evacuation, and
 3. Safe and timely patient transfer.
- B.** When performing office-based surgery using sedation, a physician shall not use any drug or agent that trigger malignant hyperthermia.